IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

GENUS MEDICAL TECHNOLOGIES, LLC,	)	
Plaintiff,	)	**Case No.**
v.	)	**JURY TRIAL DEMANDED**
BRACCO DIAGNOSTICS, INC.	)	
and	)	
CIMBAR PERFORMANCE MINERALS, INC.	)	
Defendants.	)	

COMPLAINT

COMES NOW, Plaintiff Genus Medical Technologies, LLC, and for its Complaint against Defendants, Bracco Diagnostics, Inc. and Cimbar Performance Minerals, Inc., states and alleges as follows:

PARTIES

1. Plaintiff Genus Medical Technologies, LLC ("Plaintiff" or "Genus") is a Missouri limited liability company. Genus' Members are John Edward Powers ("Ed Powers"), Matthew Strassner, Nickolas Berry, Timothy Gilmore, and The Roberts Law Firm. Each member resides in and is a citizen of the State of Missouri.

2. Defendant Bracco Diagnostics, Inc. ("Bracco") is a Delaware corporation with its principal place of business in New Jersey. It is a part of the Bracco Group, an Italian multinational conglomerate.

3. Defendant Cimbar Performance Minerals, Inc. ("Cimbar") is a Georgia corporation with its principal place of business in Chatsworth, Georgia.

JURISDICTION AND VENUE

4. Genus brings this action under Sections 4 and 16 of the Clayton Antitrust Act ("Clayton Act"), 15 U.S.C. §§ 15 and 26, to remedy violations of Sections 1 and 2 of the Sherman Act ("Sherman Act"), 15 U.S.C. §§ 1 and 2. Genus also asserts state tort law claims.

5. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1332(a)(1), 1337, and 1367. This Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1337 because Genus asserts claims arising under federal antitrust laws; specifically Genus brings this action under the Clayton Act to remedy Defendants' violations of the Sherman Act. This Court has supplemental jurisdiction over Genus' state-law claims under 28 U.S.C. § 1367 because all of the claims arise from the same facts and circumstances and form part of the same case or controversy. This Court also has diversity jurisdiction under 28 U.S.C. § 1332 because this is an action between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, as to each Defendant.

6. Personal jurisdiction over Genus' federal antitrust claims is proper under Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendants transact business in this district and are found here. Among other things, Bracco and/or its agents sell Barium Sulfate Suspension Products within this district. Bracco has a dedicated sales representative for the St. Louis, Missouri area. Cimbar and/or its agents conduct business within this district, including selling barium sulfate.

7. Personal jurisdiction over Genus' state tort law claims is proper because Defendants committed tortious acts that were deliberately aimed at a Missouri plaintiff, and Defendants had

Missouri contacts related directly to the allegations in Genus' claims, as described more fully below.

8. Venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendants transact business and are found here.

9. Additionally, or alternatively, venue is proper in this District under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred here.

FACTS

10. This case concerns an illegal scheme conceived, initiated, conducted, and maintained by Bracco and its co-conspirator Cimbar to suppress competition from Genus and monopolize the United States market for barium sulfate suspensions and powders for suspension for use as oral contrast media in radiographic imaging procedures ("Barium Sulfate Suspension Products").

11. A suspension is a liquid mixture in which solid particles are dispersed throughout the liquid. Powders for suspension are mixed with liquid to become suspensions. Suspensions used as "oral contrast media" are swallowed.

12. Barium Sulfate Suspension Products are used to enhance radiographic imaging studies of the gastrointestinal tract to help physicians diagnose medical conditions, including tumors, ulcers, polyps, hernias, and strictures. They are also used in examining dysphagia (difficulty swallowing). The more serious conditions they are used to detect include esophageal and stomach cancer, which the National Cancer Institute estimates will account for 2.6% of all new cancer cases diagnosed in 2019 (approx. 45,160 cases) and 4.4% of all cancer deaths in 2019

(approx. 27,220 cases).[1] These products are necessary for certain radiographic imaging procedures, and there is no substitute for them.

13. Barium Sulfate Suspension Products are made by combining barium sulfate with various ingredients, including sweeteners and flavoring agents, to create a thick, milk-like solution that patients drink before their radiographic imaging studies.

14. The barium sulfate coats the inside of the stomach, esophagus, and intestines. It absorbs x-rays because of its high atomic number; this contrasts the gastrointestinal tissues from surrounding tissues, making it easier for physicians to diagnose problems. It has low solubility, which means that it passes through the body rather than being absorbed.

15. Barium sulfate has been in clinical use for radiographic imaging studies for over 100 years. It is on the World Health Organization's Model List of Essential Medicines.[2]

16. Before Genus entered the market in 2015, Italian multinational Bracco controlled 100% of the United States market for Barium Sulfate Suspension Products. Bracco had enjoyed this complete monopoly since Mallinckrodt (then a division of Covidien plc) exited the market in or around August 2009.

17. When Bracco profited from a complete monopoly, Barium Sulfate Suspension Products were on the national drug shortage list month after month. This had a substantial impact on patients in the form of cancelled and rescheduled procedures. Medical providers likewise suffered from rising costs.

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[1] *See* National Cancer Institute, Cancer Stat Facts: Esophageal Cancer, https://seer.cancer.gov/statfacts/html/esoph.html; Cancer Stat Facts: Stomach Cancer, https://seer.cancer.gov/statfacts/html/stomach.html (last visited November 22, 2019).

[2] *See* World Health Organization, Model List of Essential Medicines (2019), https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1 (last visited November 22, 2019).

18. Bracco markets its barium sulfate products under the names E-Z™ and Smoothies. The E-Z™ and Smoothies lines include suspensions and powders for suspension, as well as tablets and pastes.

19. Bracco also sells other products, including injectable iodine contrast media. Although some of Bracco's products are used in other types of imagining procedures (for example, ultrasound procedures), barium sulfate is used exclusively in radiographic (for example, x-ray) procedures. Barium Sulfate Suspension Products and injectable iodine contrast media are used for different purposes in imaging procedures. Hospitals and outpatient facilities need both types of contrast media in order to provide a full range of tests.

20. Upon information and belief, Bracco has used (and continues to use) its monopoly power in Barium Sulfate Suspension Products to force customers to buy its other products. Specifically, upon information and belief, Bracco conditions the purchase of its suspension products on the purchase of its injectable contrast media and other products.

21. Defendant Cimbar is the largest producer of medical-grade barium sulfate in the world, and it sells the barium sulfate that Genus and Bracco use in manufacturing their competing Barium Sulfate Suspension Products. Cimbar supplies Bracco with a USP grade[3] barium sulfate ingredient called "Bariscan," which Bracco uses to manufacture its Barium Sulfate Suspension Products. Cimbar also manufactures a barium sulfate ingredient (hereinafter, "the Ingredient"), which Genus currently uses to manufacture its own Barium Sulfate Suspension Products. Because Cimbar does not sell suspension products, but instead sells an ingredient used in *manufacturing* radiographic imaging suspension products, it does not compete with either Genus or Bracco.

[3] A product that is "USP grade" is one that meets standards set by the United States Pharmacopeial Convention.

22. Cimbar is also the only manufacturer of medical-grade barium sulfate in the world; it manufactures its barium sulfate ingredients in a facility that is registered with FDA as an active pharmaceutical ingredients ("API") manufacturer, and its API is used in the only finished barium sulfate products approved by FDA for distribution in the United States.

23. Plaintiff Genus is headquartered in Chesterfield, Missouri. Genus was founded in 2014 by three veterans of the medical supply industry with the goal of creating a competitive alternative in the market for Barium Sulfate Suspension Products. Genus' slogan, "Choice Matters," is prominently displayed on the company's website:[4]

24. In January 2015, Genus launched its first Barium Sulfate Suspension Product under the brand name Vanilla SilQ™. In June 2015, Genus began marketing a medium-density version of the product, Vanilla SilQ MD™, and subsequently launched a high-density version, Vanilla SilQ HD™.

25. Genus initially used Bariscan as the API to manufacture Vanilla SilQ™. Genus now uses the Ingredient. Bariscan and the Ingredient come from the same manufacturing batches, and they are functionally indistinguishable.

[4] Genus Medical Technologies, https://genusmedical.com/ (last visited November 25, 2019).

26. Vanilla SilQ™ is unique in that it consists of vanilla smoothies or powders for mixing, plus flavor packets. The flavor packets allow hospitals to purchase only one product and eliminate excess inventory due to stocking multiple flavors, while still giving patients a choice of flavors.

27. Vanilla SilQ™ was well-received, and Genus quickly began taking market share away from Bracco.

28. About 80% of the Barium Sulfate Suspension Products sold in the United States are purchased by Group Purchasing Organizations ("GPOs") and independently contracted health systems (such as SSM Health). The GPOs and health systems negotiate contracts every three to five years. When Genus entered the market, there were only a handful of GPOs in the United States, including Resource Optimization, & Innovation, LLC ("ROi"); MedAssets, Inc. ("MedAssets"); HealthTrust Purchasing Group, L.P. ("HealthTrust"); Ascension Health Resource and Supply Management Group, LLC ("Ascension"); Novation, LLC ("Novation"); and Premier, Inc. ("Premier").[5]

29. The remainder of the market primarily consists of imaging centers.

30. On January 1, 2015, Genus entered into a two-year contract with MedAssets for the sale of Vanilla SilQ™ products. The MedAssets contract was later extended for an additional year. In April 1, 2015, Genus was awarded a three-year contract with ROi. In October 2015, Genus contracted with Ascension. Imaging centers and health systems also began buying Genus' products.

[5] Currently, there are even fewer GPOs. In 2015, Vizient, Inc. ("Vizient") merged with UHC, Novation's parent company. Then, in or around early 2016, Vizient purchased MedAssets' GPO segment. In or around October 2019, HealthTrust acquired ROi.

Bracco Uses the U.S. Regulatory Process to Target Genus

31. Bracco began targeting Genus soon after Genus was formed.

32. Bracco first attempted to use the U.S. regulatory process to erect barriers for Genus and gain exclusivity for its products that competed with Genus'.

33. When Genus entered the market, Barium Sulfate Suspension Products were classified as drugs in an "unapproved other" category by FDA.

34. The "unapproved other" category includes products with a long history of clinical use, such as caffeine tablets and sodium fluoride rinses. Products in the "unapproved other" category are sold without going through the FDA approval process.

35. After learning that Genus planned to market competing products, Bracco initiated contact with FDA and proposed bringing certain of its Barium Sulfate Suspension Products into a process for securing drug approval. FDA agreed that Bracco could seek approval for its barium products.

36. In December 2014, Bracco submitted a New Drug Application ("NDA") seeking approval for Barium Sulfate Suspension Products that competed with Genus'.

37. On July 30, 2015, Bracco informed FDA that "companies" were introducing Barium Sulfate Suspension Products similar to its own without approval. FDA asked Bracco to send in its concerns so they could be forwarded to the Office of Compliance of FDA's Center for Drug Evaluation and Research. Importantly, prior to this time, FDA had not required that Barium Sulfate Suspension Products receive drug approval.

38. On its website, Bracco claims it invested in the FDA approval process because "it is committed to providing customers and patients with high quality, compliant products."[6] However, Bracco is content to sell unapproved barium sulfate products that do not compete with Genus' products.

39. For example, at the time of its discussions with FDA, Bracco sold other unapproved barium sulfate products, including E-Z-Paste cream and E-Z-Disk tablets, that did not compete with Genus' suspension products. As of the date of this Complaint, these products have never been approved by FDA. Bracco also currently sells an unapproved barium sulfate suspension used in enemas, Liquid Polibar Plus. Because this product is not for oral use, it does not compete with Genus' suspension products.[7]

40. Bracco's FDA drug approval process was ongoing through 2015, and Bracco received FDA approval on January 11, 2016.

41. The approval of Bracco's products required FDA to evaluate them for multi-year "New Chemical Entity" exclusivity.

42. Bracco's clear objective was to obtain exclusivity from FDA, either by express grant or simply by erecting significant financial and regulatory barriers for Genus.

43. Ultimately, FDA denied exclusivity for Bracco's products on October 25, 2016.

44. As a result of Bracco's actions, however, FDA decided to require approval for Genus' products.

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[6] *See* Bracco Diagnostics, E-Z-HD (barium sulfate) for oral suspension, https://imaging.bracco.com/us-en/products/fluoroscopy/e-z-hd (last visited November 25, 2019).

[7] None of the unapproved Bracco products listed in this paragraph are barium sulfate suspensions or powders for suspension for use as oral contrast media. Thus, they fall outside the relevant product market in this case (the market in which Genus competes and that Bracco is attempting to monopolize).

45. On May 2, 2017, FDA sent a letter to Genus directing that Genus "discontinu[e] the manufacturing and distribution of all of [its] unapproved drugs immediately" and warning that failure to do so could "result in legal action without further notice, including, without limitation seizure and injunction."

46. On May 12, 2017, Bracco sent a letter to FDA regarding Genus' continued promotion and marketing of unapproved barium sulfate products.

47. On May 19, 2017, Genus responded to FDA. Genus explained that, consistent with the language in the Federal Food, Drug, and Cosmetic Act ("FDCA"), Barium Sulfate Suspension Products should be classified as devices rather than drugs.

48. While it prepared to challenge FDA's classification of barium sulfate as a drug and its approval requirement, Genus nonetheless began preparing to embark on the FDA drug approval process in May 2017, in case its challenge to the classification was unsuccessful. The process is costly and requires $400,000.00 in application fees, along with annual fees of approximately $250,000.00 following drug approval. These costs did not exist for Genus prior to Bracco's decision to seek FDA approval for its products.

49. On July 31, 2017, Bracco sent a letter to FDA demanding that FDA shut down Genus' sale of Barium Sulfate Suspension Products because Genus' products were not approved as drug products. Bracco also sent a copy of the letter to Genus at its Chesterfield, Missouri office.

50. This was despite the fact that Bracco did sell—and continues to sell—its own unapproved Barium Sulfate Suspension Products. Bracco's website even addresses this issue in

an FAQ that assures customers that it is okay to use Bracco barium sulfate products that have not been FDA-approved.[8]

51. Thus, Bracco embarked on an effort to secure a government-sanctioned monopoly in the market for Barium Sulfate Suspension Products by voluntarily getting its product approved by FDA, in an unsuccessful effort to gain exclusivity and a successful strategy (unless Genus' current judicial challenge to FDA's classification decision is victorious) to erect significant financial and regulatory barriers for start-up Genus. However, Bracco did not stop there. Bracco also enlisted its barium sulfate supplier, Cimbar, to try and prevent Genus from manufacturing its product at all and to make it impossible for Genus to secure FDA approval. In the meantime, Bracco also slandered Genus with customers in order to take Genus' business.

Bracco and Cimbar Conspire to Prevent Genus from Manufacturing or Securing FDA Drug Approval for Vanilla SilQ™

52. Upon information and belief, Bracco is Cimbar's largest customer, and the two companies have enjoyed a longstanding relationship.

53. As part of the drug approval process, FDA requires applicants to submit chemistry, manufacturing and controls ("CMC") data on raw materials.

54. Early in its FDA application and approval process, Bracco took steps to ensure that Genus could not easily access the raw material data for Bariscan (which both Bracco and Genus were using at the time to manufacture their Barium Sulfate Suspension Products).

55. On or about September 26, 2014, Bracco requested a meeting with FDA to discuss its plan to submit the CMC data on barium sulfate within its new drug application. This was an unusual step, as a Drug Master File ("DMF") containing this data is typically filed with FDA, so

[8] *See* Bracco Diagnostics, E-Z-HD (barium sulfate) for oral suspension, https://imaging.bracco.com/us-en/products/fluoroscopy/e-z-hd (last visited November 25, 2019).

that finished drug manufacturers can refer to the DMF in their applications for approval to market in the United States.

56. A DMF allows the manufacturer to submit data confidentially. The manufacturer can then authorize applicants to incorporate the data by reference. In this way, a manufacturer can easily make data available to multiple applicants while safeguarding any confidential or proprietary information.

57. FDA allowed the CMC data for Bariscan to be submitted within Bracco's new drug application instead of in a DMF.

58. Cimbar provided the CMC data directly to Bracco so that Bracco could include the data in its application. Cimbar would have been the only possible source for this data, and Cimbar admitted to providing Bracco with this data in one late-2018 conference call with Genus.

59. On or around March 30, 2017, Genus learned that Cimbar would no longer offer Bariscan on the open market. However, Cimbar has continued to sell Bariscan to Bracco (which secured FDA approval for products made with Bariscan). This was confirmed during a 2018 conference call with a Cimbar executive, who informed Genus that Cimbar was only selling Bariscan to a single large customer (i.e., Bracco).

60. After entering its exclusive dealing agreement with Bracco for Bariscan, Cimbar refused multiple attempts by Genus to discuss finding a replacement. However, in April 2017, Genus learned from a Cimbar sales representative about another barium sulfate ingredient offered by Cimbar (the Ingredient), which comes from the very same manufacturing batches as Bariscan. Genus then began purchasing and using the Ingredient.

61. Although the Ingredient comes from the very same manufacturing batches as Bariscan, Cimbar does not label the Ingredient's portion of these batches as USP-grade. As a

result, while Genus has been able to continue manufacturing its products using the Ingredient, it incurs an additional expense in having to independently verify the USP quality of the Ingredient that it purchases.

62. In or around March 2018, Genus requested CMC data from Cimbar relating to the Ingredient so that Genus could complete its own FDA drug application. For several months, Genus received no reply.

63. The CMC data that Genus requested from Cimbar (relating to the Ingredient) was the same data that Cimbar had previously provided Bracco (relating to Bariscan) to support Bracco's new drug application. Because the Ingredient and Bariscan come from the same manufacturing batches, the two ingredients are functionally indistinguishable.

64. Finally, in September 2018, Genus contacted Cimbar's V.P. of Sales and Marketing, Jim Gledhill. Through Mr. Gledhill, Cimbar agreed to provide the CMC data. At Cimbar's request, Genus signed a non-disclosure agreement in order to facilitate the transmission of this data.

65. In a December 27, 2018 email to Gledhill, Genus President Ed Powers emphasized that Genus was not asking Cimbar for any information "that was not already disclosed to Bracco."

66. In January 2019, Cimbar suddenly changed its position and refused to provide the data related to the Ingredient.

67. Specifically, on January 4, 2019, Mr. Gledhill emailed Mr. Powers at his office in Chesterfield, Missouri, and stated:

> After a great deal of internal discussion we've decided not to move forward on trying to validate the [Ingredient] with Genus. At this time it's simply not the direction we want to take.
>
> I regret that we have reached this conclusion since we've spent time, money and energy getting to this point.

68. Even after repeated requests, Cimbar has never provided the CMC data to Genus, despite previously providing the same data to Bracco.

69. Cimbar has refused to provide the CMC data to Genus pursuant to an agreement between Cimbar and Bracco. Cimbar's refusal serves no legitimate business purpose and only serves to undermine Genus' business and help Bracco.

70. Cimbar's refusal to provide this data is undermining Genus' business. Specifically, customers have refused to do business with Genus because its products are not FDA-approved, and Cimbar (at Bracco's behest) has erected a roadblock to securing approval by refusing to provide the necessary data.

71. Genus can only acquire the necessary data from Cimbar; there is no alternative source for this data.

72. Furthermore, Genus cannot simply purchase barium sulfate ingredients manufactured by another company (and then request CMC data from that company). Cimbar is the world's only manufacturer of barium sulfate that has been approved as an API in finished drug product applications; as such, Genus must purchase and use Cimbar's barium sulfate ingredients (and obtain Cimbar's CMC data) if it wants to secure FDA approval for its Barium Sulfate Suspension Products.

73. Because a significant and growing portion of the customer base will not purchase unapproved Barium Sulfate Suspension Products, Cimbar's refusal to provide data that Genus needs to file for drug approval is threatening Genus' ability to stay in business.

Aftermath and Continued Anti-Competitive Conduct

74. On February 28, 2019, Genus filed a lawsuit in the United States District Court for the District of Columbia against FDA, seeking declaratory and injunctive relief. Genus' lawsuit

specifically requests that FDA's designation of barium sulfate products as "drugs" be vacated, and that these products be designated as "devices" under the FDCA. Genus' lawsuit remains pending.

75. While Genus contested the regulatory barriers created by Bracco's machinations, Bracco has proceeded to smear Genus and otherwise restrain Genus through anti-competitive means.

76. Upon information and belief, Bracco and/or its agents have targeted Genus' actual and potential customers and informed them that Genus would soon be off the market.

77. Bracco's website cautions customers against purchasing from the "one other company selling barium sulfate products in the U.S.," as "those products may be subject to immediate enforcement action at any time, without prior notice."[9]

78. In late 2018, Genus learned that Bracco and/or its agents had told a third-party medical distributor and large Genus customer that "Genus will be off the market at any time." This statement was false. Bracco and/or its agents made the comment to scare Genus' customers into buying Bracco's products, instead.

79. In June 2017, MedAssets abruptly informed Genus that it was terminating their contract.

80. On or about October 25, 2017, ROi informed Genus that it would stop buying Vanilla SilQ™ products under their contract. In explaining its decision, ROi informed Genus that a third party had shown ROi FDA's warning letter to Genus. Upon information and belief, this third party was Bracco.

[9] *See* Bracco Diagnostics, E-Z-HD (barium sulfate) for oral suspension, https://imaging.bracco.com/us-en/products/fluoroscopy/e-z-hd (last visited November 25, 2019).

81. Upon information and belief, sometime prior to this date Bracco also stated or implied to ROi that Genus would soon be off the market.

82. Around the same time Genus lost the ROi contract, bidding was due on the Premier contract. Genus was blocked from bidding. Genus was likewise blocked from bidding on contracts with Vizient, Premier, SSM Health, and various other independently contracted health systems. Various imaging centers similarly refused to do business with Genus.

83. Upon information and belief, Bracco's anti-competitive actions and false statements resulted in Genus losing the ROi and MedAssets contracts and being blocked from bidding on other GPO and health system contracts.

84. Bracco currently holds approximately 85% of the market for Barium Sulfate Suspension Products. The other 15% has been retained by Genus as a result of its contract with Ascension and its sales to imaging centers.

85. Without the CMC data that Cimbar is withholding, Genus may be forced to go out of business and remove its products from the market, as Genus cannot obtain FDA approval without this data, and not enough customers will purchase unapproved products to sustain Genus' business.

86. Genus' need for the CMC data that Cimbar is withholding may persist regardless of the outcome of its pending lawsuit against FDA in the District of Columbia. If Genus prevails in that lawsuit, Barium Sulfate Suspension Products will be reclassified as "devices," but FDA will likely still require Genus to submit Cimbar's barium manufacturing data with its application to have Vanilla SilQ™ cleared as a medical device.

87. If Genus was able to secure FDA approval or clearance, then it would be able to compete to attract customers it has lost (including GPOs), attract new customers, retain existing customers, and stay in business.

CLAIMS

88. Genus restates, re-alleges, reaffirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

89. The relevant product market in this case is the market for barium sulfate suspensions and powders for suspension for use as oral contrast media ("Barium Sulfate Suspension Products"). These products are necessary for certain radiographic imaging procedures, and there is no substitute for them. Genus and Bracco are the only competitors in this market in the United States, and they make rival Barium Sulfate Suspension Products.

90. The relevant geographic market in this case is the United States. Genus and Bracco compete nationwide in the market for Barium Sulfate Suspension Products, and they are the only two competitors in this market nationally.

91. Bracco has market power and monopoly power in the United States market for Barium Sulfate Suspension Products. Bracco previously enjoyed 100% market share for these products. Since Genus's entry into the market, Bracco has controlled approximately 85% market share. This degree of concentration evidences Bracco's market and monopoly power.

COUNT I - RESTRAINT OF TRADE VIOLATION OF SHERMAN ACT (15 U.S.C. § 1) AGAINST BRACCO AND CIMBAR

92. Genus restates, re-alleges, reaffirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

93. Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce." 15 U.S.C. § 1.

94. Bracco has entered into a conspiracy with Cimbar to restrain competition from Genus and strengthen Bracco's nationwide monopoly in the market for Barium Sulfate Suspension Products. Restraining Genus and monopolizing this market are the specific objectives of Defendants' conspiracy and conduct, which have no legitimate business purpose or pro-competitive justification.

95. In furtherance of its conspiracy with Bracco, Cimbar has since January 2019 refused to provide Genus with CMC data that Genus needs in order to file for FDA drug approval (or device clearance). Without this approval, Genus cannot continue to compete with Bracco in the market for Barium Sulfate Suspension Products, as a significant and growing portion of the market will not purchase unapproved Barium Sulfate Suspension Products. As Genus is Bracco's sole competitor in this market, Cimbar's refusal to provide this data threatens to exclude Genus from the market and give Bracco a total monopoly.

96. The CMC data that Genus seeks from Cimbar relates to a Cimbar-manufactured barium sulfate ingredient (the Ingredient) that Genus has used since 2017 in manufacturing its Barium Sulfate Suspension Products. Genus can only acquire this data from Cimbar; there is no alternative source for the data.

97. Genus cannot simply purchase barium sulfate ingredients manufactured by another company (and then request CMC data from that company). Cimbar is the world's only manufacturer of barium sulfate used in FDA-approved products; as such, Genus must purchase and use Cimbar's barium sulfate ingredients (and obtain Cimbar's CMC data) if it wants to secure FDA approval or clearance for its Barium Sulfate Suspension Products.

98. Genus began asking Cimbar for this data in early 2018. After months of feigning that it would work with Genus and provide this data, in January 2019 Cimbar revealed that it had

no intention of doing so. The only explanation that Cimbar has offered for its refusal to provide Genus with this data is that it is "simply not the direction [Cimbar] want[s] to take."

99. The CMC data that Cimbar refuses to provide is the same data that it provided to Bracco to assist with Bracco's drug approval process. Although the data that Cimbar provided to Bracco is related to another Cimbar ingredient called Bariscan, the Ingredient comes from the very same manufacturing batches, and the two ingredients are functionally indistinguishable. Thus, Genus only needs data that Cimbar has already provided to Bracco. Also, Genus entered a non-disclosure agreement with Cimbar to facilitate the transmission of this data, and specifically asked for the same data that Cimbar had provided to Bracco. Thus, Cimbar has no legitimate business or trade secret reason for withholding this data from Genus.

100. Cimbar is withholding the CMC data at Bracco's behest, in a deliberate effort to strengthen Bracco's market power by making it impossible for Genus to secure FDA drug approval.

101. Genus has lost multiple customers and the opportunity to bid for contracts with new customers because its Barium Sulfate Suspension Products lack FDA drug approval. In particular, Genus has lost bidding opportunities with Vizient and with multiple health systems and imaging centers since it first requested data from Cimbar in early 2018. Securing drug approval will allow Genus to attract new business; but Genus cannot do this without the data that Cimbar refuses to provide.

102. As Barium Sulfate Suspension Products comprise most of Genus' product line and most of its sales, Cimbar's refusal to provide this data threatens to not only give Bracco a monopoly in the relevant market but also put Genus out of business altogether.

103. Also in furtherance of Defendants' conspiracy, in March 2017 Cimbar stopped selling Bariscan to any customer other than Bracco. Both Genus and Bracco had used Bariscan in manufacturing their Barium Sulfate Suspension Products.

104. After entering its exclusive dealing agreement with Bracco for Bariscan, Cimbar refused multiple attempts by Genus to discuss finding a replacement. In April 2017, Genus learned from a Cimbar sales representative about another Cimbar ingredient (the Ingredient) from the very same manufacturing batches as Bariscan, which Genus then began purchasing and using. Because Cimbar does not certify that the Ingredient is USP grade, Genus must independently verify the USP quality of the Ingredient that it purchases using external laboratories at its own expense.

105. Bracco is still manufacturing its Barium Sulfate Suspension Products using Bariscan. This is clear from the fact that Bracco secured FDA approval for suspension products made with Bariscan, and continues to sell these products. This was also confirmed during a 2018 conference call with a Cimbar executive, who informed Genus that Cimbar was only selling Bariscan to a single large customer (i.e., Bracco).

106. Both (a) Cimbar's refusal to provide Genus with data related to the Ingredient and (b) Cimbar's refusal to sell Genus Bariscan represent attempts to starve Genus of key items that it needs to continue making and selling Barium Sulfate Suspension Products. The only party benefitting from these actions is Bracco, which seeks to reclaim its total monopoly in Barium Sulfate Suspension Products when Genus fails. As such, these actions by Cimbar evidence its conspiracy with Bracco to restrain trade, put Genus out of business and give Bracco a total nationwide monopoly.

107. As Bracco and Cimbar's conspiracy has harmed (and threatens to destroy) Bracco's sole competitor in a market where Bracco already has approximately 85% market share,

Defendants' conspiracy is substantially foreclosing this market, which further demonstrates Bracco's substantial market power.

108. Defendants' conspiracy has horizontal effects in the United States market for Barium Sulfate Suspension Products because it undermines Bracco's only competitor in this market and helps give Bracco a total monopoly.

109. Defendants' conspiracy and conduct have no legitimate business purpose or procompetitive justification or effects. Even if defendants' conduct had some procompetitive effects, these effects could have been realized through less restrictive means.

110. Bracco's conspiracy with Cimbar is an unreasonable restraint on trade that is both *per se* illegal and illegal under Rule of Reason analysis.

111. Bracco's conspiracy with Cimbar violates Section 1 of the Sherman Act, 15 U.S.C. § 1.

112. Genus has suffered and will continue to suffer antitrust injury as a result of Bracco and Cimbar's violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

COUNT II – MONOPOLIZATION, ATTEMPT TO MONOPOLIZE AND CONSPIRACY TO MONOPOLIZE IN VIOLATION OF SHERMAN ACT (15 U.S.C. § 2) AGAINST BRACCO AND CIMBAR

113. Genus restates, re-alleges, reaffirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

114. Section 2 of the Sherman Act makes it unlawful to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2.

115. Bracco possesses monopoly power in the United States market for Barium Sulfate Suspension Products. Before Genus entered this market, Bracco enjoyed 100% market share. When Genus introduced its suspension product, Vanilla SilQ™, in January 2015, Genus became

Bracco's only competitor in this market; Bracco's market share subsequently dropped to approximately 85% as a result.

116. Upon Genus' entry into the relevant market, Bracco began engaging in predatory and anticompetitive conduct in a willful attempt to maintain and enhance its monopoly power by excluding its competitor Genus from the market.

117. First, Bracco attempted to obtain a government-sanctioned monopoly. Specifically, Bracco voluntarily submitted its Barium Sulfate Suspension Products to the FDA's new drug approval process. The sole purpose of this effort was strengthening Bracco's monopoly power.

118. After securing drug approval in January 2016, Bracco conspired with Cimbar to exclude Genus from the United States market for Barium Sulfate Suspension Products and ensure Bracco's monopoly. Ensuring Bracco's monopoly was the agreed-upon objective of Defendants' conspiracy.

119. In furtherance of its conspiracy with Bracco, Cimbar abruptly stopped selling its barium sulfate ingredient Bariscan to any customer other than Bracco in March 2017. Genus was forced to switch to a Cimbar ingredient (the Ingredient) from the very same manufacturing batches as Bariscan, in order to continue production. Because Cimbar does not certify that the Ingredient is USP grade, Genus must independently verify the Ingredient's USP quality using external laboratories at its own expense.

120. Then in January 2019, in furtherance of its conspiracy with Bracco, Cimbar refused (and still refuses) to provide to Genus with CMC data related to the Ingredient – data that Genus needs in order to seek FDA drug approval (or device clearance) for its Barium Sulfate Suspension Products. Genus can only acquire this data from Cimbar; there is no alternative source for the data.

121. Genus cannot simply purchase barium sulfate ingredients manufactured by another company (and then request CMC data from that company). Cimbar is the world's only manufacturer of barium sulfate used in FDA-approved products; as such, Genus must purchase and use Cimbar's barium sulfate ingredients (and obtain Cimbar's CMC data) if it wants to secure FDA approval or clearance for its Barium Sulfate Suspension Products.

122. The CMC data that Cimbar refuses to provide is the same data that it previously provided to Bracco to assist with Bracco's drug approval process. Although the data that Cimbar provided to Bracco is related to Bariscan, the Ingredient comes from the very same manufacturing batches as Bariscan, and the two ingredients are functionally indistinguishable; thus, Genus only needs data that Cimbar has already provided to another company. Also, Genus entered a non-disclosure agreement with Cimbar to facilitate the transmission of this data, and specifically asked for the same data that Cimbar had provided to Bracco. Thus, Cimbar has no legitimate business or trade secret reason for withholding this data from Genus.

123. Cimbar is withholding the CMC data at Bracco's behest, in a deliberate effort to strengthen Bracco's monopoly power by making it impossible for Genus to secure FDA drug approval.

124. Bracco and Cimbar's predatory and anticompetitive conduct has helped Bracco maintain its 85% market share of the United States market for Barium Sulfate Suspension Products.

125. Furthermore, Bracco and Cimbar's predatory and anticompetitive conduct threatens to put Genus out of business, which would return Bracco to 100% control of the relevant market. Defendants' willful attempt to further monopolize this market has a dangerous probability of success.

126. Specifically, Genus has lost multiple customers and the opportunity to bid for contracts with new customers as a direct result of its inability to obtain FDA drug approval, and it cannot file for this approval without the CMC data that Cimbar refuses to provide. In particular, Genus has lost bidding opportunities with Vizient and with multiple health systems and imaging centers since it first requested data from Cimbar in early 2018. A significant and growing portion of the market will not purchase Barium Sulfate Suspension Products that lack FDA drug approval, and such products comprise most of Genus' product line and most of its sales. As a result, Genus needs FDA drug approval in order to stay in business. Thus, Cimbar's refusal to provide the CMC data that Genus needs in order to file for FDA drug approval threatens to put Genus out of business altogether, in turn giving Bracco a total nationwide monopoly in the market for Barium Sulfate Suspension Products.

127. Bracco and Cimbar's predatory and anticompetitive conduct is motivated by their shared intent to secure Bracco's nationwide monopoly in the market for Barium Sulfate Suspension Products by destroying Bracco's only competition in this market.

128. Bracco and Cimbar's conspiracy and conduct have no legitimate business purpose or procompetitive justification or effects.

129. Bracco's willful efforts to maintain its monopoly power in the United States market for Barium Sulfate Suspension Products violate Section 2 of the Sherman Act, 15 U.S.C. § 2.

130. Bracco's attempt to enhance its monopoly power in this market violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

131. Bracco and Cimbar's conspiracy to maintain and enhance Bracco's monopoly power in this market violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

132. Genus has suffered and will continue to suffer antitrust injury as a result of Bracco and Cimbar's violations of the Sherman Act, 15 U.S.C. § 2.

COUNT III – TORTIOUS INTERFERENCE WITH CONTRACTS AGAINST BRACCO

133. Genus restates, realleges, re-affirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

134. Genus is, and at all relative times was, the only provider of Barium Sulfate Suspension Products in the United States other than Bracco.

135. Genus contracted with ROi, a group purchasing organization for hospitals, to sell its Barium Sulfate Suspension Products to the members of ROi's group.

136. Genus also contracted with MedAssets, another group purchasing organization, to sell its Barium Sulfate Suspension Products to the members of MedAssets' group.

137. Bracco also contracted with ROi and MedAssets to sell its Barium Sulfate Suspension Products to the members of either group.

138. Bracco had actual knowledge that Genus had contracted with ROi and MedAssets, and/or knew of such facts and circumstances that would have led a reasonable person to believe that these contractual relationships existed.

139. Bracco intentionally interfered with Genus' contractual relationship with ROi and caused ROi to terminate its contract with Genus.

140. Bracco likewise intentionally interfered with Genus' contractual relationship with MedAssets and caused MedAssets to terminate its contract with Genus.

141. Bracco employed improper means in inducing ROi and MedAssets to terminate their contracts with Genus. Specifically:

a. Bracco misrepresented to ROi and MedAssets that Genus was going to be off the market in a short period of time. These misrepresentations were made in 2017, before Cimbar had communicated to Genus its refusal to provide CMC data;

b. Bracco conspired with Cimbar and created an unlawful restraint of trade by agreeing that Cimbar would refuse to sell Genus Bariscan, an ingredient that Genus had used in manufacturing its Barium Sulfate Suspension Products, and would exclusively sell Bariscan to Bracco;

c. Bracco conspired with Cimbar and created an unlawful restraint of trade by agreeing that Cimbar would withhold CMC data from Genus, leaving Genus unable to apply for FDA drug approval;

d. Bracco created an unlawful restraint of trade by requiring purchasers of its Barium Sulfate Suspension Products to also purchase its injectable contrast media; and/or

e. Bracco monopolized, attempted to monopolize and/or conspired with Cimbar to monopolize the United States market for Barium Sulfate Suspension Products through the foregoing actions.

142. Bracco's interference with Genus' contractual relationships lacks any justification or excuse.

143. As a direct and proximate result of Bracco's actions, Genus was damaged in that it lost the ability to sell its Barium Sulfate Suspension Products to ROi and MedAssets' members for a minimum of three years.

144. Bracco's actions were taken in a willful, wanton, and malicious manner with the express purpose of excluding Genus, Bracco's only competitor, from the United States market for

Barium Sulfate Suspension Products, thereby enhancing Bracco's market and monopoly power in this market.

COUNT IV – TORTIOUS INTERFERENCE WITH BUSINESS EXPECTANCY AGAINST BRACCO

145. Genus restates, realleges, re-affirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

146. Genus is, and at all relative times was, the only provider of Barium Sulfate Suspension Products in the United States market other than Bracco.

147. Genus had a valid and reasonable business expectancy to contract with GPOs and health systems which together purchase approximately 80% of all Barium Sulfate Suspension Products sold in the United States.

148. Genus had a valid and reasonable business expectancy to contract with the imaging centers that comprise most of the remainder of the United States market for Barium Sulfate Suspension Products.

149. Genus had previously contracted with GPOs such as ROi, MedAssets, and Ascension.

150. Genus had previously contracted with various health systems and imaging centers.

151. Genus had a valid and reasonable business expectancy when it began contract negotiations with Vizient, Premier, and various health systems and imaging centers.

152. Bracco had actual knowledge that Genus was going to contract to sell its Barium Sulfate Suspension Products to these GPOs, health systems, and imaging centers; and/or Bracco knew of such facts and circumstances that would have led a reasonable person to believe that such a business expectancy existed.

153. Bracco induced Vizient, Premier, and various health systems and imaging centers not to do business with Genus (i.e., refuse to let Genus bid for contracts and/or refuse to purchase Genus' products).

154. Bracco employed improper means in inducing Vizient, Premier, health systems and imaging centers not to do business with Genus. Specifically:

a. Bracco misrepresented that Genus was going to be off the market in a short period of time;

b. Bracco conspired with Cimbar and created an unlawful restraint of trade by agreeing that Cimbar would refuse to sell Genus Bariscan, an ingredient that Genus had used in manufacturing its Barium Sulfate Suspension Products, and would exclusively sell Bariscan to Bracco;

c. Bracco conspired with Cimbar and created an unlawful restraint of trade by agreeing that Cimbar would withhold CMC data from Genus, leaving Genus unable to apply for FDA drug approval;

d. Bracco created an unlawful restraint of trade by requiring purchasers of its Barium Sulfate Suspension Products to also purchase its injectable contrast media; and/or

e. Bracco monopolized, attempted to monopolize and/or conspired with Cimbar to monopolize the United States market for Barium Sulfate Suspension Products through the foregoing actions.

155. Bracco's interference with Genus' business expectancy lacks any justification or excuse.

156. As a direct and proximate result of Bracco's actions, Genus was damaged in that it lost its business expectancy with GPOs and was locked out of a substantial portion of the United States market for Barium Sulfate Suspension Products.

157. Bracco's actions were taken in a willful, wanton, and malicious manner with the express purpose of excluding Genus, Bracco's only competitor, from the United States market for Barium Sulfate Suspension Products, thereby enhancing Bracco's market and monopoly power in this market.

COUNT V – CIVIL CONSPIRACY AGAINST BRACCO AND CIMBAR

158. Genus restates, realleges, re-affirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

159. Bracco and Cimbar agreed and conspired to exclude Genus from the United States market for Barium Sulfate Suspension Products and enhance Bracco's market and monopoly power in this market. Defendants also agreed and conspired to injure and/or destroy Genus' business, without justification or excuse.

160. The unlawful objectives of Defendants' conspiracy included allowing Bracco to require purchasers of its Barium Sulfate Suspension Products to also purchase its injectable contrast media; Bracco's ability to make such demands of customers is strengthened by its market and monopoly power.

161. Bracco and Cimbar committed the following acts in furtherance of their conspiracy:

a. Bracco and Cimbar conspired to prevent Genus from obtaining FDA drug approval for its Barium Sulfate Suspension Products by agreeing that Cimbar withhold CMC data from Genus that Genus needs in order to seek approval;

b. Bracco and Cimbar conspired to prevent Genus from obtaining Bariscan, a barium sulfate ingredient that Genus had used in manufacturing its Barium Sulfate

Suspension Products, by agreeing that Cimbar would sell this ingredient only to Bracco;

c. Bracco required purchasers of its Barium Sulfate Suspension Products to also purchase its injectable contrast media, tying the two types of products together; and/or

d. Bracco misrepresented the soundness of Genus' business to its current and future customers by intentionally and deceptively informing them that Genus would soon be off the market.

162. As a direct and proximate result of Bracco and Cimbar's actions, Genus was damaged in that it lost its contracts with ROi and MedAssets, and was prevented from contracting with Vizient, Premier and various health systems and imaging centers.

163. Bracco's actions were taken in a willful, wanton, and malicious manner with the express purpose of excluding Genus, Bracco's only competitor, from the United States market for Barium Sulfate Suspension Products, thereby enhancing Bracco's market and monopoly power in this market.

COUNT VI – UNJUST ENRICHMENT AGAINST BRACCO

164. Genus restates, realleges, re-affirms, and incorporates by reference all preceding paragraphs as if fully set forth herein.

165. Bracco was enriched by receipt of excess profits resulting from its unlawful monopolization of the United States market for Barium Sulfate Suspension Products, as more particularly described above;

166. Bracco's enrichment was at the expense of Genus, the only other supplier of Barium Sulfate Suspension Products in the market;

167. Bracco retained the excess profits without payment to Genus;

168. Retention of excess profits by Bracco would be unjust because they were obtained unlawfully, as more particularly described above.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Genus demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Genus respectfully requests that this Court:

(a) Enter judgment in Genus' favor, and against Defendants Bracco and Cimbar, declaring that Defendants have violated Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2; and are liable for tortious interference with contract, tortious interference with a business expectancy, civil conspiracy and unjust enrichment;

(b) Award Genus treble damages with respect to its federal antitrust claims under Section 4 of the Clayton Act, 15 U.S.C. § 15; compensatory and punitive damages with respect to its state law claims; and the cost of suit and reasonable attorneys' fees;

(c) Permanently enjoin Defendants Bracco and Cimbar from (1) conspiring to restrain trade in the United States market for Barium Sulfate Suspension Products; (2) monopolizing, attempting to monopolize and conspiring to monopolize this market; and (3) preventing Genus from purchasing Bariscan;

(d) Grant injunctive relief requiring that Cimbar provide Genus with the data that it needs to file for FDA drug approval or device clearance; and

(e) Award any additional relief that the Court deems just and appropriate.

Dated: November 26, 2019

Respectfully submitted,

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